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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,061	11/27/2001	Max Schaldach	7163-32	3174

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EXAMINER	
THALER, MICHAEL H	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,061	SCHALDACH ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *7,9-13,19,20,35-40 and 42-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,14-17,21-34,41,51 and 52* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/27/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Invention I and the species of figure 1 in the reply filed on May 19, 2004 is acknowledged. The traversal is on the ground(s) that an election between Inventions I and II should not be required since the examiner has not demonstrated that the stent of claim 1 may be made by another and materially different process than that of claim 19. This is not found persuasive because the process as claimed in claim 19 can be used to make another and materially different product. For example, it could be used to make a stent comprising tissue which is not elastic, noting that claim 1 requires the tissue to be elastic. Upon reconsideration, claims 1-6, 8, 14-18, 21-34, 41, 51 and 52 are generic.

Claims 7, 9-13, 19, 20, 35-40 and 42-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 19, 2004. Contrary to applicant's remarks, claims 44 and 47 do not read on the elected species since they directly or indirectly depend from claim 43 which is admitted by applicant as being drawn to a non-elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claim 18 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 18 has not been further treated on the merits.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8, 14-17 and 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, lines 2-3, it is not understood what "portion wise manner" means. Claims 30-34 are unclear for the same reason. In claim 8, line 2, there is no antecedent basis for "the hardening agent". The preamble of claim 14 indicates that the stent is not part of the claimed combination ("for implanting a stent"). However, claim 14 depends from claim 1 in which the stent is positively recited as being claimed. Thus, the scope of claim 14 is unclear. Claim 16 is indefinite for the same reason.

Claims 14-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The preamble of claim 14 indicates that the stent is not part of the claimed combination. However, claim 14 depends from claim 1 in which the stent is positively recited as being claimed. Claim 16 has the same problem.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

> differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 21 and 25 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Atala (2003/0208279). Atala discloses a stent 10 inherently capable of being deployed in a coronary artery (note the term "blood vessels" in paragraphs [0002] and [0013]) comprising a tubular body (figure 1) for expansion from a first condition to a second condition (paragraph [0063]) wherein the tubular body includes at least a first wall portion comprising human or animal tissue (paragraphs [0013] and [0041]) of adequate elasticity (paragraph [0063]). Alternatively, it would have been obvious that the Atalá stent is capable of being deployed in a coronary artery since it is small enough to fit into blood vessels. As to claims 5 and 25, the Atala tissue is inherently capable of being hardened if and when a hardening agent is applied thereto.

Claims 4, 22-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (2003/0208279). Atala fails to disclose the tissue being genetically modified. However, it is old and well known in this art to genetically modify tissue in order to obtain favorable characteristics for

it. It would have been obvious to genetically modify the Atala tissue so that it too would have this advantage.

Claims 1, 2, 5, 6, 25 and 30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Turi (5,556,414). Turi discloses a coronary stent 20 (col. 1, lines 40-42) comprising a tubular body (figure 1) for expansion from a first condition to a second condition (col. 8, lines 1-5) wherein the tubular body includes at least a first wall portion (the wall of the entire composite prosthesis 20) comprising human or animal tissue (26) of adequate elasticity. Alternatively, it would have been obvious that the tissue 26 of the Turi stent 20 has adequate elasticity since it expands with the cylindrical member 22. As to claims 6 and 30, Turi discloses hardening agent (the adhesive described in col. 5, lines 49-52).

Claims 4, 8, 22-24, 26-29, 32-34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414). As to claims 4 and 22-24, Turi fails to disclose the tissue being genetically modified. However, it is old and well known in this art to genetically modify tissue in order to obtain favorable characteristics for it. It would have been obvious to genetically modify the Turi tissue so that it too would have this advantage. As to claims 8 and 41, Turi fails to disclose

the hardening agent (adhesive) enclosed in microcapsules. However, it is old and well known in this art to enclose adhesive in microcapsules in order to obtain the advantage of easily deploying the adhesive on the surface. It would have been obvious to enclose the Turi adhesive in microcapsules so that it too would have this advantage.

Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turi (5,556,414) in view of Atala (2003/0208279). Turi fails to disclose the tissue being cartilage (noting that claims 31 and 33 indirectly depend from claim 3). However, Atala teaches that tissue on a stent should be cartilage (paragraph [0041]) apparently in order to make the stent biocompatible(paragraph [0013]). It would have been obvious to make the Turi tissue cartilage so that it too would have this advantage.

Claims 14-17, 51 and 52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berg et al. (5,680,873). As to these claims, which, as best understood, do not include the stent as being part of the claimed combination, Berg et al. disclose a catheter which is inherently capable of implanting a stent comprising a distal end region (the distal portion of the balloon catheter described in col. 10, lines 13-16 and col. 11, lines 1-3), a

holding device for holding the stent (the balloon on the balloon catheter which is inherently capable of holding a stent placed thereon) and sheathing device 22 characterized in that an application device (the feed passage of guide catheter 22 through which dye passes as described in col. 7, lines 17-20) is provided at the sheathing device for applying a medium which is capable of flow to a surface of the stent. Alternatively, it would have been obvious that the Berg et al. balloon catheter is capable of implanting a stent since stents are frequently implanted by a balloon. As to claim 15, Berg et al. disclose an application opening (at the extreme distal end of guide catheter 22). As to claim 16, the Berg et al. sheathing device 22 has an anti-adhesion coating 40.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
7/13/04

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731